24 July 2025
EMA/CHMP/227935/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Voranigo

vorasidenib

On 24 July 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Voranigo[2], intended for the treatment of low grade astrocytoma or oligodendroglioma with an isocitrate dehydrogenase-1 (IDH1) *R132* or isocitrate dehydrogenase-2 (IDH2) *R172* mutation in adults and adolescents from 12 years of age weighing at least 40 kg. The applicant for this medicinal product is Les Laboratoires Servier.

Voranigo will be available as 10 mg and 40 mg film-coated tablets. The active substance of Voranigo is vorasidenib, an antineoplastic agent (ATC code: L01XM04). Vorasidenib is an inhibitor that targets the mutant IDH1 and IDH2 enzymes. In patients with astrocytoma or oligodendroglioma, *IDH1* and *IDH2* mutations lead to overproduction of the oncogenic metabolite 2-hydroxyglutarate (2-HG), which results in impaired cellular differentiation contributing to oncogenesis. By inhibiting the IDH1 and IDH2 mutated proteins, vorasidenib inhibits the abnormal production of 2-HG thereby leading to differentiation of malignant cells and a reduction in their proliferation.

The benefit of Voranigo is prolonged radiographic progression-free survival in adults and adolescents with oligodendroglioma or astrocytoma with an *IDH1* or *IDH2* mutation compared with placebo, as shown in a phase 3 randomised, double-blind, placebo-controlled clinical study. The most common side effects with Voranigo include increased liver enzymes (ALT, AST, GGT), fatigue and diarrhoea.

The full indication is:

> Voranigo as monotherapy is indicated for the treatment of predominantly non-enhancing Grade 2 astrocytoma or oligodendroglioma with an IDH1 R132 or IDH2 R172 mutation in adult and adolescent patients aged 12 years and older and weighing at least 40 kg who only had surgical intervention and are not in immediate need of radiotherapy or chemotherapy (see section 5.1).

Treatment with Voranigo should be initiated and supervised by physicians experienced in the use of

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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cancer medicinal products.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.